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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,469	05/25/2006	Suk-Hyung Kwon	0070777-000020	1471

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EXAMINER
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HIRIYANNA, KELAGINAMANE T

ART UNIT	PAPER NUMBER
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1633

NOTIFICATION DATE	DELIVERY MODE
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11/19/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/580,469	<b>Applicant(s)</b> KWON ET AL.	
	<b>Examiner</b> KELAGINAMANE T. HIRIYANNA	<b>Art Unit</b> 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 7, 8 and 10-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7, 8 and 10-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>05/25/2006</u> .  | 6) <input type="checkbox"/> Other: _____                          |

Applicant's response filed on 07/23/2008 in response to office action mailed on 06/27/2008 has been acknowledged.

### **Restriction of invention**

Applicant's election without traverse of restriction requirement in the reply filed on 07/23/2008 is acknowledged. Applicant elects, without traverse, the invention Group III (Claims 7, 8 and 10-13) for further prosecution on merits. Applicant's further election of species is noted.

Claims 7, 8, 10 and 12 are amended.

Claims 7, 8 and 10-13 *are pending and are examined in this office action.*

*Applicants are required to follow Amendment Practice under revised 37 CFR §1.121. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.*

### **Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 7, 8 and 10-13 are rejected under 102(a) as being anticipated by Ha et al., (2003, Calcified Tissue International, 72: 395).

The above claims are drawn to a method of preventing or treating metabolic bone disease comprising administering Sophorae fructus to a subject in need and in further limitation said disease is osteoporosis and treated by stimulating osteoblast proliferation, the secretion of growth factors and generation of nitric oxide in the

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osteoblast wherein the growth factor is IGF-1 or TGF-beta and further inhibiting secretion of cytokines such as IL-1 or IL-6 or osteoclast differentiation.

Ha teaches a method of preventing or treating bone loss and osteoporosis by orally administering herbal extract from *Sophorae flavescentis* or *sophorae flos* (Abstract). Ha further teaches such administration induced proliferation of osteoblast like cell (Abstract). Ha teaches that the herbal extract contained ample quantities of phytoestrogen (genestein), consumption which has been shown prevent bone loss by stimulating osteoblastic bone formation and preventing osteoclastic bone resorption in the prior art. *Sophorae fructus* being a closely related to above species of *Sophorae*, it is inherent that it too comprised of same bone therapeutic principles in its extract. Absent reason to believe otherwise the secretion of growth factors IGF-1 or TGF-beta involved in bone reformation and inhibition of bone resorptive cytokines occur and the disease is prevented or treated. Thus the rejected claims are within the scope of the Ha's disclosure.

Claims 7, 8 and 10-13 are rejected under 102(b) as being anticipated by Ha et al., (2002, Korean Patent Publication No: 1020020044745 A; published on 06/19/2002; art of record).

The above claims are drawn to a method of preventing or treating metabolic bone disease comprising administering *Sophorae fructus* to a subject in need and in further limitation said disease is osteoporosis and treated by stimulating osteoblast proliferation, the secretion of growth factors and generation of nitric oxide in the osteoblast wherein the growth factor is IGF-1 or TGF-beta and further inhibiting secretion of cytokines such as IL-1 or IL-6 or osteoclast differentiation.

Regarding claims 7, 8, and 10 Ha teaches a method of preventing or treating bone loss and osteoporosis by orally administering herbal extract from *Sophorae flos* (Abstract). Ha teaches that the herbal extract contained ample quantities of phytoestrogen (genestein), consumption which has been shown prevent bone loss by stimulating osteoblastic bone formation and preventing osteoclastic bone resorption in the prior art. *Sophorae fructus* being a closely related to above species of *Sophorae*, it

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is inherent that it too comprised of the same bone therapeutic principles in its extract. Absent reason to believe otherwise the secretion of growth factors IGF-1 or TGF-beta involved in bone reformation and inhibition of bone resorptive cytokines occur and the disease is prevented or treated. Thus the rejected claims are within the scope of the Has's disclosure.

### **Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7, 8 and 10-13 are rejected under 35 USC 103 (a) as being unpatentable over Ha et al., (2002, Korean Patent Publication No: 1020020044745 A; published on 06/19/2002; art of record) in view of Spelsberg et al (1999, Mol. Endocrinol. 13:819-828) and Suh et al (2003, Phytochemistry 63:209-215).

The above claims are drawn to a method of preventing or treating metabolic bone disease comprising administering Sophorae fructus to a subject in need and in further limitation said disease is osteoporosis and treated by stimulating osteoblast proliferation, the secretion of growth factors and generation of nitric oxide in the osteoblast wherein the growth factor is IGF-1 or TGF-beta and further inhibiting secretion of cytokines such as IL-1 or IL-6 or osteoclast differentiation.

Regarding claims 7, 8, and 10 Ha teaches a method of preventing or treating bone loss and osteoporosis by orally administering herbal extract from Sophorae flos (Abstract). Ha teaches that the herbal extract contained ample quantities of phytoestrogen (genestein), consumption which has been shown prevent bone loss by stimulating osteoblastic bone formation and preventing osteoclastic bone resorption in the prior art. Sophorae fructus being a closely related to above species of Sophorae, it is inherent that it too comprised of same bone therapeutic principles in its extract. Ha however, does not disclose the details of the molecular mechanisms behind phytoestrogen action in the abstract.

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Spelsberg however, teaches regarding the limitations in claim 10-13 regarding the cellular mechanisms associated with estrogen mediated bone therapy (entire article, abstract; Fig.1; Fig.3; Table.1; p.626) wherein he teaches stimulating osteoblast proliferation, secretion of growth factors IFF-1 and TGF-beta1 and decrease of IL-1beta and IL-6 and inhibition of osteoclast differentiation (entire article, abstract; Fig.1; Fig.3; Table.1; p.626).

Su et al teaches that the phytohormone genistein (present in plants including Sophorae sps.) treatment of osteoblast cells causes inhibition of their TNF induced apoptosis by decreasing IL-6 but did not decrease nitric oxide (NO) (abstract; Fig.4; p.213, col.1, paragraphs 3-4 bridging col.2).

Thus it would have been obvious for one of ordinary skill in the art to incorporate in the method of treating osteoporosis with the phytohormones in the extracts of Sophorae species as taught by Ha et al the steps of analyzing their effects on osteoblasts and osteoclasts for the increase or decrease of the marker factors including IGF-1, cytokines including IL-6 and NO production to quantitatively determine the bone growth. One of ordinary skill in the art would have reasonable expectation of success making using extracts from plant species Sophorae fructus for treating osteoporosis in subjects in need and further quantitate its cellular effects in bone growth and resorption because art teaches that making and using of the extracts from closely related Sophorae species for treating osteoporosis as routine. Thus, the claimed invention was *prima facie* obvious.

### **Conclusion:**

No claim allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Kelaginamane Hiriyanne Ph.D.*, whose telephone number is **(571) 272-3307**. The examiner can normally be reached Monday through Thursday from 9 AM-7PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Joseph Woitach Ph.D.*, may be reached at **(571) 272-0739**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR)

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system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). When calling please have your application serial number or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. For all other customer support, please call the USPTO call center (UCC) at (800) 786-9199.

Kelaginamane T. Hiriyanne

Patent Examiner

Art Unit 1633

/Robert M Kelly/

Primary Examiner, Art Unit 1633